

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

ESPERION THERAPEUTICS, INC.,

Plaintiff,

-against-

DAIICHI SANKYO EUROPE GMBH,

Defendant.

No. 1:23-cv-02568-ER

**FEDERAL RULE OF CIVIL PROCEDURE 26(f) CONFERENCE REPORT**

Pursuant to Federal Rule of Civil Procedure 26(f), counsel for the parties held a teleconference on Friday, June 2, 2023 and have subsequently communicated regarding the scheduling issues addressed herein. Plaintiff's counsel proposed a mutual exchange of positions on those issues in advance of this filing, in the hopes of submitting a joint report. However, after the parties exchanged drafts, counsel for the Defendant indicated that it would not agree to submit jointly a report that included Plaintiff's draft and, absent Plaintiff revising its draft, proposed to submit separate reports to the Court. To ensure that both parties have a full and fair opportunity to submit their respective positions, Plaintiff agreed to proceed in that matter. The following report summarizes Plaintiff's view of the case, the time necessary to undertake discovery, and the importance of proceeding expeditiously to trial, and Defendant will file separately a report that summarizes the same.

**A. Subjects on Which Discovery Might Be Needed.**

Plaintiff Esperion Therapeutics, Inc. is a trailblazing company that offers innovative drugs for the treatment of cardiovascular disease. For more than 15 years, Esperion has been developing

bempedoic acid, a breakthrough medicine for patients with high LDL cholesterol who do not have other treatment options. Defendant Daiichi Sankyo Europe GmbH (“DSE”) is the European affiliate of Daiichi Sankyo Company, Ltd., a large pharmaceutical conglomerate based in Japan. In 2019, DSE won a coveted license from Esperion to sell its bempedoic acid drugs in Europe—an exclusive right potentially worth more than \$1 billion to DSE. In exchange, DSE agreed to pay Esperion, among other consideration, a \$300 million milestone payment at a critical stage in the drug’s development: when it demonstrated a “cardiovascular risk reduction” rate of at least 20% in a landmark clinical trial called the CLEAR Outcomes Study and obtained regulatory approval of a new label.

Milestone payments like the one DSE agreed to pay Esperion are critical to the development of innovative drug treatments. They are a common feature of pharmaceutical licensing contracts and the well-developed financial structure of the drug development ecosystem. A license like the one at issue in this case is essentially a partnership between two companies: one company (Esperion) incurs the enormous up-front risks and costs of developing a drug over many years and, depending on the results, the other company (DSE) compensates it for shouldering that burden and for the right to profit from its hard work.

The \$300 million milestone payment is at the heart of the partnership between Esperion and DSE—and is at the heart of this lawsuit. Esperion began developing bempedoic acid drugs in 2008 and incurred substantial risk by investing many years and hundreds of millions of dollars in the product, including bearing the costs of the global CLEAR Outcomes Study with nearly 14,000 patients at more than 1,200 sites in 32 countries. The milestone payment was a critical and material financial term in the parties’ contractual relationship.

The CLEAR Outcomes Study concluded in November 2022, and the results were spectacular. The study demonstrates Esperion's bempedoic acid drug reduces "cardiovascular risk" by more than 20%, including a 27% reduction in non-fatal heart attacks and 23% reduction in the composite of nonfatal and fatal heart attacks. These results triggered the \$300 million milestone payment and should have been cause for celebration at both Esperion and DSE. After all, the success of the study meant that DSE held the exclusive right to market and sell breakthrough medical treatments in Europe to millions of patients with or at high risk for cardiovascular disease—the culmination of more than 15 years of innovation and hard work by Esperion, in partnership with DSE.

But DSE had a different plan. It repudiated its contractual obligation to make the \$300 million milestone payment in the apparent hope that its refusal to pay would serve as leverage to force Esperion back to the negotiating table to accept less money. DSE knew that, given the materiality of the \$300 million payment, Esperion—as a company publicly traded on NASDAQ—was required to disclose DSE's repudiation to the investing public. DSE knew that its refusal to pay the \$300 million milestone payment would cause Esperion to suffer financial distress or potentially ruin.

In defense of its repudiation, DSE offered a strained and untenable interpretation of the parties' mutual agreement—one which it knows is contrary to the unambiguous letter of the agreement and to the parties' intent. After sitting with the CLEAR Outcome Study results for months, DSE attacked the data—which had been peer-reviewed and published in the New England Journal of Medicine—and concocted a novel, baseless interpretation of the parties' agreement. In March 2023, DSE told Esperion for the first time that it would not make any regulatory milestone payment, allegedly because the CLEAR Outcomes Study did not demonstrate a sufficient

reduction in one particular composite result called MACE-4—only one of many data points evaluated in the study.

This interpretation of the parties’ agreement is wrong on its face: the milestone payment is based on “cardiovascular risk reduction,” not MACE-4 specifically. In fact, during the negotiation of the contract, the parties had expressly considered and rejected DSE’s proposal to limit the regulatory milestone payment to MACE-4, choosing instead the broader “cardiovascular risk” term.

DSE’s repudiation inflicted immediate and substantial harm on Esperion, causing its stock to plummet 54% in a single day. That harm is ongoing and Esperion’s stock price remains below \$2 per share. As one analyst report noted, this lawsuit is “potentially disruptive to the company ramping its commercial efforts ahead of the label expansion . . . and in need of a speedy resolution,” especially “[w]ith ESPR trading at ~\$1.5/share.” J.P. Morgan, *Esperion Therapeutics: Latest Thoughts and Key Takeaways from Cholesterol Survey* (Apr. 4, 2023). Again, this ongoing and substantial harm to Esperion is knowing and deliberate—part of DSE’s commercial strategy to put maximum pressure on Esperion and force it back to the bargaining table to renegotiate the terms of the agreement.

Esperion did not acquiesce. Instead, it filed a single-count declaratory judgment action in this Court, seeking a declaration that it is entitled to the \$300 million milestone payment upon regulatory approval. While Esperion could have filed additional claims based on DSE’s misconduct, it deliberately filed a narrow single-count declaratory judgment action because of the heightened need for prompt resolution.

The Declaratory Judgment Act (DJA) and Federal Rule of Civil Procedure 57, which implements the DJA, were specifically designed to resolve a case like this, in which an aggrieved

party requires the prompt determination of a contractual dispute to confirm its rights and protect against further harm. *See Beacon Constr. Co., Inc. v. Matco Elec. Co., Inc.*, 521 F.2d 392, 399 (2d Cir. 1975) (DJA, Rule 57, and Rule 1 “shall be construed to secure the just, speedy, and inexpensive determination of every action”); *see also Chachkes v. David*, 2021 WL 101130, at \*6 (S.D.N.Y. Jan. 12, 2021) (“[T]he issue involves a request for declaratory relief based upon what Plaintiff alleges is an impairment of the exercise of his contractual rights. Thus, not only is the motion formally ripe for adjudication, but the interest of justice weighs in favor of resolving it without delay.”).

This is a straightforward case. It involves the interpretation of a single sentence in a single paragraph of a single contract. This is not a complex commercial litigation involving multiple parties and multiple claims. DSE implicitly recognized that this case is ready for prompt resolution when it answered the amended complaint and requested a declaratory judgment that is the mirror image of Esperion’s claim but did not assert any counterclaims. Both parties, in other words, agree that issue has been joined and that this case is ripe and should be heard expeditiously. In fact, the discovery process is already underway: Esperion has served document requests, and the parties are actively negotiating a protective order and ESI protocol. Importantly, the anticipated scope of discovery is narrow: the negotiation and drafting of the License Agreement; the parties’ understanding of the terms of the License Agreement and performance thereunder; the CLEAR Outcome Study results; and DSE’s position that Esperion is not entitled to the \$300 million milestone payment.

Because this is a straightforward case, Esperion has been and will continue to be substantially harmed by DSE’s repudiation, and time is of the essence. Esperion has proposed a reasonable case schedule that gives the parties more than four months to complete fact discovery

and more than six months to complete all discovery. Esperion and DSE are both sophisticated parties represented by large law firms that can efficiently litigate the single disputed issue in this case.

When Esperion initiated the Rule 26(f) process and proposed the below schedule, DSE immediately dragged its feet and made clear its intention to delay, delay, delay. DSE first refused even to meet for 10 days, claiming unavailability for a 15-minute telephone call. When it finally showed up for a call, on June 2, DSE was unprepared to discuss multiple issues during the parties' required Rule 26(f) conference. DSE has since argued, contrary to the clear text of Rule 26 and Rule 34, that Esperion's document requests, served after the Rule 26(f) conference, are somehow premature and that it should not have to respond within the timeframe set by the Federal Rules.

The purpose of the DJA is to "provid[e] a speedy and inexpensive method of adjudicating legal disputes." *Leopard Marine & Trading, Ltd. v. Easy Street Ltd.*, 896 F.3d 174, 188 (2d Cir. 2018) (quoting *Garanti Finansal Kiralama A.S. v. Aqua Marine & Trading Inc.*, 697 F.3d 59, 70 (2d Cir. 2012)). Esperion respectfully submits that DSE's refusal to agree to a case schedule that will ensure a prompt resolution of this dispute is part and parcel of its strategy of applying maximum pressure on Esperion—knowing that the markets will be inhospitable to Esperion during the pendency of this litigation and delaying the \$300 million payment as long as possible. The Court should not countenance further delay-and-stonewall tactics by DSE. Esperion's proposed case schedule and discovery plan are fair, reasonable, and should be adopted in full by the Court.

#### **B. Electronically Stored Information.**

The parties anticipate the need for electronic discovery and have taken steps to ensure the preservation of relevant documents and electronically stored information. The parties are working

in good faith to develop a mutually agreeable plan regarding the discovery of electronically stored information.

### **C. Case Schedule**

The issues in this case are straightforward and discovery can be completed speedily. Esperion asserts a single claim for declaratory relief based on a discrete issue of contract interpretation, and DSE admits that the declaratory relief it seeks is merely “the opposite” or “a ‘mirror image’” of Esperion’s claim. ECF No. 33 at 27 n.7. Esperion proposes a case schedule that would give the parties four months to complete fact discovery and six months to complete all discovery—which is more than enough time given the narrow scope of Esperion’s declaratory judgment claim. Parties in this District and across the country complete discovery and prepare cases for trial in far less time. *See, e.g., Feldman v. Sanders Legal Grp.*, No. 7:11-cv-00494, Dkt. 13 (S.D.N.Y. Oct. 11, 2011) (setting deadline for completion of all discovery 3.5 months after entry of scheduling order); *Nemchik v. Wells Fargo Bank, N.A.*, No. 1:14-cv-02475, Dkt. 19 (S.D.N.Y. June 27, 2014) (setting fact discovery deadline 3 months after entry of scheduling order, and expert discovery deadline less than 5 months after entry of scheduling order).

Specifically, Esperion proposes a case schedule that would provide more than two months for the substantial completion of document production, two months for the parties to conduct fact depositions after document production is completed, and two months for expert discovery. Esperion’s proposed discovery deadlines are listed below:

1. Deadline for substantial completion of document production: **August 18, 2023**
2. Deadline for completion of fact depositions: **October 13, 2023**
3. Deadline for service of expert reports: **October 18, 2023**
4. Deadline for service of rebuttal expert reports: **November 17, 2023**

5. Deadline for completion of all discovery: **December 11, 2023**

This proposed schedule is fair and reasonable given the narrow scope of the issues in this case. This case involves a single declaratory judgment claim concerning the interpretation of one contractual provision. There is one plaintiff and one defendant. The issues in this case are straightforward, and discovery will focus on discrete topics, such as the negotiation and drafting of the contract.

DSE argues that a more prolonged case schedule is necessary to prepare for summary judgment and/or trial, but offers nothing beyond generic assertions regarding the burdens of discovery in support of its position. For example, it argues that Esperion's proposed schedule is unreasonably short given the "complexity" of the case, but does not explain why a declaratory judgment claim on the interpretation of a single contractual provision is "complex." Finally, DSE argues that an extended case schedule is necessary because it is located in Germany and subject to European data privacy laws. But Esperion already served its initial requests for production of documents on DSE on June 2—DSE can begin the process of collecting responsive documents now, and has more than two additional months to substantially complete document discovery under Esperion's proposed schedule.

Esperion also respectfully requests that the Court set a trial date in April 2024, if the Court is available. DSE offers no basis for prolonging the schedule for an additional six months beyond delay. Esperion expects to obtain regulatory approval as early as the first half of 2024, which would immediately entitle Esperion to the milestone payment. Prompt resolution of Esperion's declaratory judgment claim is necessary so this controversy regarding the parties' contractual rights and obligations is resolved no later than when the milestone payment is due.



Finally, Esperion has already been substantially harmed by DSE's repudiation of its payment obligation and will continue to be harmed as long as this contractual dispute remains unresolved. As described above, when DSE's repudiation became public, Esperion's stock plummeted 54% in a single day. The unresolved controversy regarding DSE's repudiation has continued to harm Esperion in the market: several months later, Esperion's stock price remains below \$2 per share. Any further delay in resolving the parties' dispute will cause further harm to Esperion—both by delaying the payment to which Esperion is contractually entitled and causing continued harm to Esperion in the market.

Esperion respectfully requests that the Court adopt the case schedule in its proposed Case Management Plan and Scheduling Order, which is attached as Exhibit A.

**D. Claims of Privilege or Protection.**

Subject to modification by the parties, all claims of privilege or protection as trial materials, and the production of any information subject to such claims, will be governed by Federal Rule of Civil Procedure 26 and this Court's Local Civil Rule 26.2. The parties are in good faith negotiating a proposed protective order addressing these issues to present to the Court for approval.

**E. Changes to Limitations on Discovery.**

**1. Plaintiff's Position**

Esperion respectfully requests that Local Civil Rule 33.3 not apply in this action. Because Esperion's amended complaint asserts a single declaratory judgment claim on a discrete issue of contract interpretation, Esperion expects the scope of the interrogatories in this case to be narrow. It would be most efficient if the parties are permitted to serve now any narrow interrogatories they believe would promote prompt resolution of the case. Esperion therefore believes the sequencing of interrogatories contemplated by Local Rule 33.3 would be inefficient under the circumstances.

Esperion does not believe any other changes to the limitations on discovery are necessary at this time.

Dated: June 23, 2023  
New York, New York

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